February 9, 2000

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20857

Re: Pre-market Approval of Silicone Inflatable Breast Prostheses, 64 Fed. Reg. 45,155 (August 19, 1999); and Medical Devices, Exemption from Pre-market Notification and Reserved Devices, 65 Fed. Reg. 2296 (January 14, 2000)

Dear Ms. Kahan:

Thank you for your response letter of November 16, 1999 that addressed concerns raised in a September 9, 1999 letter submitted to FDA by the Office of Advocacy. The subject of these letters dealt with the final rule establishing pre-market approval requirements for silicone inflatable breast prostheses. Copies of both letters have been enclosed to refresh your recollection. At this writing, Advocacy wishes to point out that in your November 16 response, and in subsequent FDA rulemakings, FDA has incorrectly interpreted section 605(b) of the Regulatory Flexibility Act (RFA).

Section 605(b) allows an agency to certify that a rulemaking will not have a significant economic impact on a substantial number of small entities once that agency has made a preliminary assessment as to the impact of a particular proposal. The definitions of "significant" and "substantial" are not defined anywhere in the RFA. Congress intended this to be the case so that agencies would be forced to analyze each of their proposed regulations in the context of numerous variables like the economy and the types of industries affected. The absence of a particularized definition, however, does not mean that Congress left the terms completely ambiguous or open to unreasonable interpretations. The legislative history of the RFA reveals that "substantial number" is intended to mean a substantial number of entities within a particular economic or other activity.[1] The intent, therefore, was not to require that agencies find that a large number of the entire universe of small entities would be affected by a rule, but that a proportionately large number of the entities affected by the rule are small. For example, if there are five businesses affected by a regulation, and one of those businesses is small, then a substantial number of small entities—one hundred percent of small entities in the industry—are impacted, and twenty percent of the entire industry are impacted.

Keeping the legislative intent in mind, when FDA stated in its November 16 letter that only two (out of a possible seven) businesses would be affected by the breast prosthesis

[1] 126 CONG. REC. S10941 AND 10942 (1980) (SECTION-BY-SECTION ANALYSIS OF THE REGULATORY FLEXIBILITY ACT).

regulation, and that this did not constitute a substantial number, FDA misinterpreted the RFA. Apparently, those two entities represent 100 percent of the small entities in the industry.

The Office of Advocacy has decided to comment on FDA's interpretation at the present time because a pattern has been recently detected whereby FDA has used the incorrect interpretation in at least one other rulemaking. Specifically, on January 14, 2000, FDA published a rulemaking that will, if promulgated, exempt certain medical devices from pre-market notification (65 Fed. Reg. 2296). In that rulemaking, FDA stated that there were six manufacturers of opthalmic eye shields, and that six was not a substantial number. To the contrary, six constitutes 100 percent of the industry.

The second part of the RFA certification requires agencies to determine whether there will be a "significant economic impact." In determining whether the impact was significant for the breast prosthesis regulation," FDA apparently only considered the impact on the five manufacturers that currently have the required data and are poised to file pre-market approval (PMA) applications. This type of analysis does not reflect the anti-competitive barriers that may result from the regulation. When promulgating regulations, agencies should be careful not to erect artificial market barriers that may unnecessarily concentrate an industry. This is not to say that agencies are always expected to see into the future in order to determine how all new business formations might be affected. Rather, as in this case, it is reasonable to expect that the two small businesses that have expressed an interest in marketing the implants might be affected significantly. Apparently, the two businesses that have expressed an interest have been unable to complete the data requirements for a PMA application. An alternative approach, such as an implementation delay, may have helped these businesses compete more effectively.

For different reasons, the January 14 regulation also fails to address adequately whether or not the regulation will have a "significant economic impact." Specifically, there is no explanation of why an annual cost of $5000 per firm is not significant. The fact that SBA's data indicates that small firms with fewer than 500 employees have annual receipts of about $1.5 million means little without corresponding information about profits or some other indicator of how an annual cost of $5000 will actually impact a small firm in that particular industry. For instance, if overhead or equipment costs are especially high for this industry, or if the industry has unusually low profit margins, $5000 could be significant. Moreover, SBA's data on annual receipts covers a variety of medical device manufacturers—not just manufacturers of opthalmic devices. If the annual receipts are actually substantially below the $1.5 million figure, $5000 could be significant. At any rate, these are some of the considerations that should be applied in determining whether an impact is significant. It is not sufficient to simply state that $5000 is not significant.

Thank you for your attention to this important issue. We look forward to an ongoing dialogue with FDA on RFA matters. Please do not hesitate to contact either of us if you have any questions or comments at 202-205-6945.

Sincerely,

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cc: Stephen P. Rhodes, Center for Devices and Radiological Health
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